

**EPA Response to Comments on the
Draft Problem Formulation for Ecological Risk Assessment at Operable Unit 3,
Libby Asbestos Superfund Site, February 22, 2008
Received from MWH Americas, Inc.**

General Comment #1: The overall proposed approach and methods presume that adverse ecological impacts have occurred at OU3 and constitute an “ecological validation study” which should only be performed after the potential for ecological impacts are demonstrated.

Response: EPA does not presume that adverse ecological effects have occurred in OU3. Rather, EPA is proposing studies as part of a remedial investigation to determine whether or not any ecologically significant effects have occurred in OU3 due to the release and subsequent migration of hazardous substances and/or pollutants of contaminants from the former vermiculite mine. The overall approach proposed is consistent with current EPA ecological risk assessment guidance and practice in that it uses a “weight-of-evidence” approach to evaluate risks.

General Comment #2: The proposed approach is not cost-effective and does not give consideration to limited resources.

Response: EPA considers the cost and feasibility of performing various types of studies, and believes that all studies that are proposed are the most cost-efficient strategy to collect data of sufficient quantity and quality to support risk assessment and risk management decision making. The detailed sampling design and data quality objectives for each study that EPA proposes in OU3 will be described in a Sampling and Analysis Plan.

General Comment #3: MWH suggests that the first step in the assessment of potential risks should be the collection of population and community demographic information. It is suggested that population studies are of greater importance when little is known regarding the effects contaminants of concern can have on survival, growth, and reproduction of receptors. Toxicity testing and measurement of histopathology should be considered as next steps. They further suggest that this approach would be more cost-effective.

Response: EPA agrees that population studies are one important line of evidence that can be considered in the determination of whether ecologically significant effects are occurring at the site. However, data collected at the population and community level are inherently variable, and hence this line of evidence often requires a number of years of effort before sufficient information is collected to support reliable decision-making. Hence, EPA does not agree this should be the first line or the only line of investigation pursued at the site.

General Comment #4: MWH suggests that if aquatic toxicity testing is performed, it should be with laboratory prepared solutions of LA collected from OU3.

Response: This and other comments received on the scope the design of the aquatic toxicity testing of LA have been resolved through further discussions and the final plan for site-specific fish toxicity testing as documented in the final Phase II Sampling and Analysis Plan for Operable Unit 3, Libby Asbestos Superfund Site, Part A: Surface Water and Sediment (Phase IIA SAP).

General Comment #5: MWH states that the Problem Formulation fails to acknowledge that the geologic formation (i.e., the underlying resource that prompted development of Libby Mine) is naturally high in LA-containing vermiculite and that as a result of natural weathering, erosion and surface water runoff from surface outcrops there are contributions to the concentrations of LA in soil and sediment observed at the Site. They further suggest that laboratory toxicity testing would not account for physiological adaptations of receptors at the site.

Response: A paragraph has been added to the Problem Formulation document to acknowledge the potential for natural sources to contribute to observed levels of LA in some locations. EPA does not consider it likely that any populations of receptors at the site have developed an "adaptation" to LA, and does not consider this a relevant topic for investigation.

Specific Comment: Section 2.4.1, page 10: Tree Bark, Forest Soil and Duff, third paragraph. When will results of the tree bark and duff samples be available?

Response: The results for the tree bark samples and forest soil samples collected during the Phase I remedial investigation for OU3 have been added to the revised Problem Formulation document. The complete results for duff samples are not yet available.

Specific Comment: Section 2.4.1, page 10: The statement, "...LA was detectable in a number of soil samples collected relatively close to the mined area, but was not detectable at a distance more than 1.5 miles from the mined area" is potentially misleading. This statement fails to acknowledge natural contributions to LA at the Site, and should be clarified.

Response: The statement above is accurate and correct as written. A paragraph has been added to the Problem Formulation document to acknowledge that some LA may be associated with natural conditions.

Specific Comment: Section 3.4, page 16, Fish: Text states that fish may be exposed to asbestos in surface water, sediment and aquatic food items via ingestion. Figure 3-2 indicates that such exposures are believed to be complete and may provide an important contribution to the total risk to these receptors. What evidence is there to suggest that LA may pose a significant risk to fish through the ingestion pathway? This pathway would require gastrointestinal absorption of asbestos by fish. What evidence is there to suggest

that LA is bioavailable through the oral route of exposure in fish? No studies are cited in Attachment D, Asbestos Profile, Section 4.0, Fish that directly address asbestos exposure through ingestion. In the absence of such evidence, the ingestion pathway should be indicated as incomplete or “?” in Figure 3-2, rather than “...may provide an important contribution to the total risk to the receptor.” This qualitative statement is presumptive that LA contributes to risk to fish through the ingestion pathway.

Response: Ingested asbestos may pose risks by effects directly on the epithelial cells of the GI tract (this does not require “absorption”), and may also result from particle translocation from the GI tract into the body. Laboratory studies on fish by Belanger reveal the occurrence of asbestos in tissues such as kidney, indicating that the latter does occur. As noted above, EPA does not presume that ingestion exposure of LA does cause effects on fish, but is proposing studies to determine IF LA causes effects by any pathway. The site conceptual model for LA has been revised to identify complete exposure pathways that warrant evaluation, and to remove assumptions about the relative importance of the oral and inhalation exposure routes.

Specific Comment: Section 3.4, page 16, Benthic Invertebrates: Text states that benthic invertebrates may be exposed to asbestos in surface water, sediment and aquatic food items via ingestion. Figure 3-2 indicates that such exposures are believed to be complete and may provide an important contribution to the total risk to these receptors. What evidence is there to suggest that asbestos may pose a significant risk for benthic invertebrates through the ingestion pathway? Again, this pathway is presumptive and assumes gastrointestinal absorption of asbestos by benthic invertebrates.

Response: As noted above, EPA does not presume that oral exposure to LA does cause effects on BMI, but is proposing studies to determine IF LA causes effects by any pathway. The CSM for asbestos has been revised to identify complete exposure pathways that warrant investigation and evaluation, and to remove assumptions about the relative importance of various exposure pathways acting on a receptor. The exposure pathways for benthic invertebrates to asbestos in surface water, sediment and food items via ingestion are identified as complete.

Specific Comment: Section 3.4, page 17, Terrestrial Plants and Soil Invertebrates: Text states that soil invertebrates may be exposed to asbestos in soil by direct contact and ingestion. Figure 3-2 indicates that such exposures are believed to be complete and may provide an important contribution to the total risk to these receptors. Again, this pathway is presumptive and assumes that LA may pose a significant risk for soil invertebrates through direct contact. Studies cited in Attachment D, Asbestos Profile, Section 4.0, Soil Invertebrates describe accumulation of asbestos fibers in worms, but the potential for adverse effects is unknown. In the absence of such evidence, the direct contact pathway should be indicated as incomplete or “?” in Figure 3-2, rather than complete.

Response: As noted above, EPA does not presume that direct contact or oral exposure to LA does cause effects on soil invertebrates, but is proposing studies to determine IF LA causes effects by any pathway. The CSM for asbestos has been revised to remove

statements concerning the assumed relative importance of various pathways to total risk. The exposure pathway for soil invertebrates to LA in soil via direct contact/ingestion is identified as complete.

Specific Comment: Section 3.4, page 17, Mammals and Birds: Text states that mammals may be exposed to asbestos in soils, surface water, sediment and food via ingestion. Figure 3-2 indicates that such exposures are believed to be complete and may provide an important contribution to the total risk to these receptors. Again, this pathway is presumptive and assumes that LA may pose a significant risk for mammals through prey items and the ingestion pathway. Studies cited in Attachment D, Asbestos Profile, Section 4.0, describe exposure of mammals through the ingestion pathway, but none of them demonstrated significant effects on growth, survival, or reproduction. The only potentially adverse effect noted was histopathological effects on the lung. Changes in histopathology are difficult to link to significant effects on growth, survival, or reproduction in receptor populations. In the absence of such evidence, the ingestion pathway should be indicated as incomplete or “?” in Figure 3-2, rather than complete.

Response: As noted above, EPA does not presume that oral exposure to LA does cause effects on birds or mammals, and is proposing studies to determine IF LA causes effects by any pathway. None of the studies in Appendix D involve exposure of birds or mammals to LA, so there are no data to support the conclusion that LA does NOT cause effects of potential concern. The CSM for asbestos has been revised to remove assumptions concerning relative contributions of different pathways to total risk. Oral exposure of wildlife to LA in soils, surface water, sediment and food are identified as complete.

Specific Comment: Section 4.4, page 20, 2. Site-Specific Toxicity Tests: An additional limitation of site-specific toxicity tests is that they do not account for potential behavioral and physiological adaptations of organisms living at the site which reduce exposure to contaminants or their toxicity. Please keep in mind that the site has high naturally occurring levels of LA, and receptors inhabiting this area may have adapted mechanisms to deal with this natural constituent.

Response: EPA does not believe that aquatic or terrestrial receptors are likely to have undergone any physiological adaptation to exposures to LA asbestos in OU3. If such an adaptation were to occur, it would presumably be observable in site-specific population studies as the occurrence of a population that is less impacted than would be predicted based on toxicity studies using non-acclimated receptors. This is another reason why EPA believes it's important to consider multiple lines of evidence when assessing ecological risks and making risk management decisions within OU3.

Specific Comment: Section 4.4, page 21, 3. Population and Community Demographic Observations: The general advantages and limitations of this approach have been adequately described in this section. Population studies, however, are of greater importance when little is known regarding the effects contaminants of concern can have on survival, growth, and reproduction of receptors. Assuming an appropriate reference

area can be agreed upon; comparing population demographics could be the most efficient method of initially determining if receptors exposed to site contaminants have been adversely impacted.

Response: EPA agrees that population and community demographic data are a valuable line of evidence, especially when toxicity information on the contaminant of concern (in this case LA) is sparse. However, when evaluating population and community demographic data, EPA believes it's important to consider the potential limitations, including the inherent variability of population metrics and the selection of an appropriate reference area. EPA believes that for OU3, population and community demographic data will be valuable when considered as one line of evidence in a weight of evidence approach.

Specific Comment: Section 5.2, page 23, second paragraph: Text refers to additional sampling rounds in spring and summer of 2008, which will capture temporal and spatial variability of contaminant distribution in site media. Although surface water contaminant concentrations commonly vary temporally and spatially, sediment and soil contaminant levels rarely exhibit such variation. Contaminants are bound within the sediment or soil matrix and have little mobility. Consequently, multiple rounds of sediment and soil sampling may not be necessary. The additional surface water sampling is appropriate and should capture existing temporal or spatial variability within site water bodies.

Response: As noted previously, data are not available to evaluate potential temporal variability in sediment contamination levels, and EPA is proposing two additional rounds of sediment sampling to obtain data on this question. Multiple additional rounds of soil sampling to assess temporal trends are not proposed. Additional soil sampling may be proposed to assess the spatial extent of contamination. Study objectives, sampling design and other details will be described in a sampling and analysis plan.

Specific Comments on Section 6.2, page 25, and page 26, and page 26 fourth paragraph, first sentence pertaining to surface water toxicity testing.

Response: These specific comments pertain to the design of the surface water toxicity testing with LA. Subsequent discussions have resolved questions over this study, and the final design is documented in the final Phase IIA SAP.

Specific Comment: Section 6.2, page 27, Fish Community: When electro-shocking, attempts should be made to collect fish of the same species at each location in order to control for species-specific differences in measurement endpoints. If sufficient numbers of the same species cannot be collected at each location, members of the same subfamily should be harvested.

Response: EPA agrees that the level of tissue burden and the occurrence of histological lesions in fish may depend on the age and species of fish, and will seek to collect sufficient numbers of each type to allow meaningful data analysis. The specifics of the fish collections will be detailed in a sampling and analysis plan. For the community

survey, the data that are needed is on the types and numbers of all species that are present as well as age structure and size.

Specific Comment: Section 6.2, page 27, In-Situ Measures of Exposure and Effects: How will a link be established between the frequency and severity of histological lesions and receptor growth, survival, and reproduction? Please describe how a correlation will be made between changes in histology and significant adverse effects on populations of fish.

Response: For fish, links will be made quantitatively or qualitatively based on the results of the surface water toxicity testing and observed histopathology. For mammals and birds, EPA agrees that it may be difficult to establish a quantitative relation between tissue burden and histopathology and higher order effects on individuals and populations without substantial additional laboratory testing. For this reason, EPA plans to consider these types of data as part of the weight-of-evidence approach to identify asbestos exposure and measure effects.

Specific Comment: Section 6.3, page 28, Site-Specific Toxicity Testing: Please indicate which plant species will be used in the site-specific toxicity testing of site soils and provide evidence of its relevance to the plant communities present at the site.

Response: The details concerning plant species to be tested (if any) and the objectives will be described in a sampling and analysis plan. The problem formulation document has been revised to clarify that site-specific toxicity testing of soils in OU3 will likely only be necessary if capping and vegetative cover is considered as a remedial alternative in the feasibility study (FS). Results of site-specific toxicity testing of soils may be considered in evaluating sources of capping material and/or the long term effectiveness and permanence of a cap.

Specific Comment: Section 6.3, page 28, Site-Specific Population and Community Demographic Observations: Soil invertebrate population studies will not be performed. It is unclear if a plant community assessment is planned or is just being considered as possibly useful. If the study is planned, please provide detail regarding methodology and plant types (forbes, browse, etc.) that are proposed for characterization.

Response: The Problem Formulation document has been revised to describe each of the measurements (for each receptor group) as possible tools to be implemented for the ecological risk assessment. Specific implementation of the measurements will be specified in subsequent sampling and analysis plans. If plant and soil invertebrate toxicity testing and plant community surveys are judged to be needed, they will likely be used to support the evaluation of remedial alternatives in the FS.

Specific Comment: Section 6.4, page 28, first paragraph, second sentence: Text states "Although data from Phase I are not yet available...". Is this a reference to the tree bark and duff samples? Please clarify.

Response: This text has been edited and tree bark data are summarized. Data for duff are not yet available.

Specific Comment: Section 6.4, page 29, Biomarkers of Exposure and Effect: Is the measurement of biomarkers of exposure to asbestos planned as part of this investigation? If so, please identify these biomarkers and cite references.

Response: The biomarkers of exposure in general are asbestos tissue burdens and effects are histopathology. Specific biomarkers selected for investigation along with data quality objectives will be described in a sampling and analysis plan.

Specific Comment: Section 6.4, page 31: Text references Table 6-2, Wildlife Exposed Receptor Groups. As stated in Section 3.3, page 15, feeding guild table and preceding paragraph, "If a detailed assessment of feeding guilds is needed, the most common approach is to select a representative species to represent the group." Please identify the proposed representative species for each guild shown in Table 6-2.

Response: Indicator species will be selected by EPA in consultation with the BTAG if it is deemed necessary to quantitatively evaluate ingestion exposures for wildlife for either asbestos or non-asbestos contaminants.

Specific Comment: Section 6.4, page 31, Table of maximally exposed receptor groups: There should be some evidence that asbestos is capable of adversely impacting the prey of invertivores, herbivores, and piscivores before embarking on a costly sampling program to evaluate potential impacts at higher trophic levels. An iterative approach is recommended in which the first phase focuses on the prey groups (invertebrates, plants, fish) listed above. In addition, a worst case scenario small mammal population study should be conducted as ground invertivores are likely at a higher risk than other potentially exposed receptor groups due to their increased soil exposure.

Response: This comment assumes that effects on wildlife only occur if LA reduces the availability of prey items, and that wildlife species are not potentially affected by toxicity related to ingestion of contaminants in food items or inhalation. EPA considers ingestion of LA in prey items to be a complete exposure pathway that could be of concern to higher order predators. The studies proposed for avian and mammalian receptors are aimed at directly measuring exposure and effects on the birds and mammals.

Specific Comment: Section 6.4, page 31, Collection Methods: Text states that mammals will be collected using Sherman live traps. In the proposed iterative approach, only small burrowing mammals should be collected in the first phase of the investigation. Sherman live traps are available in different sizes for different mammals. In our experience, only the smallest Sherman live traps will prevent smaller sized shrews from escaping through cracks in the trap. Please make sure to select the appropriate trap size for these species. The suggested worst case scenario study location is near the Tailings Impoundment. For any investigative survey area, habitat for small burrowing mammals

must be present, and the area must have been impacted by mining-related activities. An appropriate reference location would need to be selected as well.

Response: These comments will be addressed in a sampling and analysis plan where the details of the small mammal collection will be provided.

Specific Comment: High levels of vermiculite and LA are naturally occurring in the mine area. Consequently, burrowing animals are exposed to high vermiculite and LA concentrations that are unrelated to historic mining activities in several of the proposed sampling locations. If sampling of small burrowing mammals is conducted for tissue and/or histopathologic analysis, sampling locations should be carefully selected to ensure that only mining-related effects are measured.

Response: These comments will be considered by EPA in the development of a sampling and analysis plan to guide the collection of small mammals. The specific sampling locations will be identified in that document along with the rationale for the selection of the sampling location. EPA agrees that small ground-dwelling animals should be the focus of the small mammal trapping, and will use appropriately sized traps. Sampling locations will be selected to characterize exposures and effects both near and far from the mine.

Specific Comment: We fail to understand how birds, particularly arboreal invertivores, are likely to receive significant exposures to LA fibers. Even resident birds have large home ranges and are unlikely to forage exclusively within the areas proposed for sampling. Furthermore, the collection of birds representative of multiple receptor groups (i.e., ground invertivores, ground herbivores/omnivores, arboreal invertivores, aquatic invertivores/omnivores, and piscivores) and from multiple locations (i.e., mined, forest and riparian) is highly presumptive that exposure pathways are complete and significant. The potential for avian exposure to LA could be tested in a much more direct and less expensive manner by sampling dietary items for these receptors to determine whether or not they are exposed to significant concentrations of LA through the ingestion pathway. If dietary items fail to contain significant levels of LA, then the ingestion pathway is unlikely to be significant for birds. As described above, sampling of small burrowing mammals would provide a worst-case assessment of the potential for exposure and risk to terrestrial animals through the inhalation pathway. If exposures and risks to small burrowing mammals from inhalation are insignificant, then it is highly unlikely that birds would receive significant exposures through this pathway. Again, we believe that an iterative, step-wise approach to the ecological risk assessment is much more rationale and will provide a more efficient use of investigation resources.

Response: EPA agrees that collection of prey items for analyses of asbestos exposures would be useful if there was a way to interpret their meaning. However, because oral toxicity reference values (TRVs) for LA are not presently available for either birds or mammals, there is presently no way to determine if any observed level of LA in the tissue of a prey item would or would not be of concern. Because the relative exposure and

sensitivity of birds and mammals to LA is unknown, EPA does not agree that use of a mammal as a surrogate for a bird is appropriate.

Specific Comment: Section 6.4, page 31, Measurement of Asbestos Tissue Burdens: If such measurements were conducted, how would LA tissue burdens be correlated with effects on receptor growth, survival, and reproduction? How will LA tissue burdens be related to significant adverse effects on populations of birds and mammals?

Response: For fish, links will be made quantitatively or qualitatively based on the results of the surface water toxicity testing and observed histopathology. For mammals and birds, EPA agrees that it may be difficult to establish a quantitative relation between tissue burden and histopathology and higher order effects on individuals and populations without substantial additional laboratory testing. For this reason, EPA plans to consider these types of data as part of the weight-of-evidence approach to identify asbestos exposure and measure effects.

Specific Comment: Section 6.4, page 32, Population and Community Demographic Observations: A quantitative small mammal population survey would be conducted in the first phase of the proposed iterative approach. Additional surveys of mammalian or avian density and diversity would not be performed.

Response: This concern was responded to as part of General Comment #3. EPA agrees that population studies are one important line of evidence that can be considered in the determination of whether ecologically significant effects are occurring at the site. However, data collected at the population and community level are inherently variable, and hence this line of evidence often requires a number of years of effort before sufficient information is collected to support reliable decision-making. Hence, EPA does not agree this should be the first line or the only line of investigation pursued at the site.

Specific Comment: Section 6.4, page 32, Additional Toxicity Testing with LA: There should be some evidence that LA is capable of adversely impacting the prey of invertivores, herbivores, and piscivores before embarking on toxicity testing on organisms at higher trophic levels.

Response: See previous responses.

Specific Comment: Section 6.5, page 33, Site-Specific Toxicity Testing: Refer to our previous comments regarding surface water sample collection, aquatic toxicity testing, and spiking studies. The same approach should be utilized when conducting the FETAX.

Response: The specific design of the toxicity testing with LA and amphibians will be detailed in a sampling and analysis plan. Due to timing of field activities, EPA does not anticipate conducting the amphibian testing in the first round of sampling for the ecological risk assessment.

Specific Comment: Section 6.5, page 33, In-Situ Measures of Exposure and Effects: What evidence is there to suggest that LA may be associated with gross or histological abnormalities in amphibians? Given that the incidence of deformities in amphibians has increased nationwide and the contributing causal factors are not well understood, this is not an appropriate measure of site-specific impacts on amphibians. In addition, frog population demographics, in general, vary considerably both temporally and spatially. Consequently, an amphibian population study at the site and an appropriate reference area would not necessarily provide useful data for this investigation.

Response: In the absence of strong evidence that exposure to LA does not cause effects in amphibians or other ecological receptors, the scope of the remedial investigation for OU3 includes data collection to investigate if exposure to LA from OU3 is causing ecologically significant effects. To the extent that amphibians may have deformities caused by other factors, that would be accounted in the comparison between exposed and control groups. EPA understands that amphibian populations vary temporally and spatially, and that is why any study of population demographics would likely be repeated several times before being considered as strong evidence. The details of the study will be described in a sampling and analysis plan.

Section 6.5, page 33, Population and Community Demographic Observations, first paragraph: Text describes the collection of amphibians from the site, and from reference areas, "...to examine and assess the frequency and severity of gross and histological abnormalities." Aside from being presumptive that LA has contributed to adverse effects in amphibians at OU3, this section fails to identify a suitable reference location. During the February 28, 2008 meeting, a wildlife refuge was proposed by the USFWS as a reference location for the Tailings Pond. A managed wildlife refuge located distant from OU3 is unlikely to represent similar geological and biological attributes as the Site. In light of the previous comment, above, regarding natural variability in amphibian populations, as well as the availability of a suitable reference location, the appropriateness of a population and demographic survey for amphibians at the Tailings Pond should be further evaluated.

Response: EPA agrees that one of the important factors in a useful population study is the selection of an appropriate reference area. The specific design of the amphibian studies and the choice of a reference area will be detailed in a sampling and analysis plan. The comments provided by MWH will be considered in the development of that document. Due to timing of field activities, EPA does not anticipate conducting the amphibian testing in the first round of sampling for the ecological risk assessment.